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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA**

IN RE: Bard IVC Filters Products Liability
Litigation,

No. MDL 15-02641-PHX-DGC

Sherr-Una Booker, an individual,
Plaintiff.

No. CV-16-00474-PHX-DGC

C. R. Bard, Inc., a New Jersey corporation,
and Bard Peripheral Vascular, Inc., an
Arizona corporation,
Defendants.

ORDER

The parties have filed various motions in limine (“MIL”) in advance of the Booker bellwether trial. The Court ruled on some of the motions in an earlier order. Doc. 10075. This order will rule on the remaining motions.

A. Defendants' MIL No. 1 (Recovery filter complications).

Plaintiff Booker was implanted with a Bard G2 filter in June 2007. The filter later tilted, migrated, and fractured. Ms. Booker had surgeries to remove the filter and several fractured struts, but one strut remains embedded in the wall of her inferior vena cava (“IVC”). Defendants seek to exclude evidence of complications with an earlier version of the Bard IVC filter – the Recovery filter – arguing that those complications are not “substantially similar” to the issues with Ms. Booker’s G2 filter. Doc. 9862 at 5-7.

1 The Recovery was Bard’s first generation of retrievable IVC filters, and was on
2 the market from the beginning of 2003 to the fall of 2005. The Recovery was followed
3 by the G2. As Defendants explain in their motion: “Based on clinical experience with
4 the Recovery Filter, Bard made several significant changes to the G2 Filter: the filter
5 hook wire diameter was increased, the filter arm tips were curved, the curvature radius of
6 the filter arms at the sleeve were increased, and the spline was modified to accommodate
7 the other dimensional changes.” *Id.* at 4. Because Ms. Booker received a G2 filter, and
8 that filter had been changed significantly from the Recovery filter, Defendants argue that
9 problems with the Recovery have “absolutely no relevance to the issues in this case.” *Id.*
10 The Court does not agree.

11 Plaintiffs claim that Bard negligently and defectively designed the G2 filter, failed
12 to warn of its risks, and did so with a mindset worthy of punitive damages. In response,
13 Defendants will argue, among other points, that the FDA cleared the G2 filter for market.
14 Defendants vigorously opposed Plaintiffs’ motion to exclude evidence of the FDA’s
15 510(k) clearance process, arguing that the steps a manufacturer must take before a
16 product is cleared by the FDA are “highly relevant to a case . . . like this one,” and that
17 compliance with the 510(k) process “is certainly probative under Georgia law on the
18 issues of reasonableness of the design, manufacture, and warnings of the G2 Filter, as
19 well as whether Bard’s conduct rises to the level justifying punitive damages[.]”
20 Doc. 9690 at 3. The Court agreed with Defendants, noting that the FDA grants 510(k)
21 clearance “only where the device ‘is as safe and effective as a [predicate device] and does
22 not raise different questions of safety and efficacy than the predicate device.’” Doc. 9529
23 at 4 (citation omitted).

24 Bard identified the Recovery filter as the predicate device for the G2, and avowed
25 to the FDA that the “design, material, components, fundamental technology (mode of
26 device function/operation) and intended use featured with the [G2]” are “substantially
27 equivalent to those featured with the predecessor Recovery Filter System[.]”
28 Doc. 10068-1 at 25. Defendants assert that “one of Bard’s goals in developing the G2

1 Filter was to reduce the number of incidents of filter fracture and migration that Bard had
2 observed with the Recovery Filter.” Doc. 9862 at 4.

3 Given these facts, the Court concludes that Bard’s knowledge of problems with
4 the Recovery filter is relevant to central issues in this case – whether Bard properly
5 designed the G2 to correct those problems, whether Bard failed to warn physicians and
6 patients about problems shared by the Recovery and G2, and whether Bard’s alleged
7 failure to correct or warn about known problems justifies an award of punitive damages.
8 The Court also concludes that it would be difficult to try this case without evidence of the
9 Recovery filter and the problems it encountered. Defendants’ evidence regarding FDA
10 clearance will necessarily include the fact that the Recovery filter was the predicate
11 device for the G2 and was substantially equivalent to the G2. In showing Bard’s care in
12 designing the G2, Defendants almost certainly will argue that Bard carefully tracked
13 problems encountered by the Recovery, dutifully reported those problems to the FDA,
14 and took specific steps to correct those problems in the G2. Defendants will use this
15 evidence to show that Bard did not negligently or defectively design the G2 and did not
16 fail to warn of its risks. It is only fair that Plaintiffs be permitted to present evidence to
17 support their claim that the Recovery was known to be more hazardous than Bard
18 admitted publicly or to the FDA, and that it involved problems that were not corrected in
19 the G2 and Bard failed to warn physician and patients of those known problems.

20 Defendants cite a number of cases for the proposition that other instances of
21 product failure are admissible only if the instances are substantially similar to the product
22 failure at issue in this case. *Id.* at 5. For example, the Ninth Circuit has held that
23 “[a] showing of substantial similarity is required when a plaintiff attempts to introduce
24 evidence of other accidents as direct proof of negligence, a design defect, or notice of the
25 defect.” *Cooper v. Firestone Tire & Rubber Co.*, 945 F.2d 1103, 1105 (9th Cir. 1991).
26 For three separate reasons, the Court does not find this case law controlling.

27 First, Ms. Booker alleges that her G2 filter tilted, perforated her IVC, fractured,
28 and migrated. Doc. 10068 at 7. These methods of failure include virtually all of the

1 known methods of failure for the Recovery filter.

2 Second, the facts of this case distinguish it from many of the cases cited by
3 Defendants. This is not simply a product defect case in which Plaintiffs seek to introduce
4 evidence of other potentially unrelated product failures. As already noted, the Recovery
5 was the predicate for the G2 and Bard sought FDA clearance on the basis that the G2 was
6 substantially equivalent to the Recovery. Bard intends to present evidence of that FDA
7 clearance during trial. Defendants surely will note that the clearance required an FDA
8 determination that the G2 was as safe and effective as the Recovery. In this context,
9 evidence regarding the safety and effectiveness of the Recovery filter is plainly relevant,
10 particularly where Plaintiffs claim that the Recovery was not as safe and effective as Bard
11 represented to the FDA. Further, Defendants claim to have designed the G2 to overcome
12 known defects in the Recovery, making the extent and severity of those defects relevant
13 to the adequacy of Bard's design of the G2.

14 Third, although substantial similarity is required by the Ninth Circuit for direct
15 evidence of negligence, design defect, or notice, it is not required when other examples of
16 product failure are used to impeach an expert's testimony that a product is safe. *Cooper*,
17 945 F.2d at 1105. The parties do not address whether the evidence in this case would be
18 used for impeachment or direct evidence.

19 Defendants also seek to exclude evidence of complications involving cephalad
20 migration (toward the heart), asserting that such evidence is irrelevant because
21 Ms. Booker's filter migrated in a caudal direction (away from the heart). Doc. 9862
22 at 7-8. Plaintiffs respond that Bard combined caudal and cephalad migration in tracking
23 adverse events internally and in reporting migration rates to the FDA. Doc. 10068 at 9
24 (citing Doc. 10068-9 at 2-4). On this record, however, the Court cannot determine
25 whether evidence of cephalad migration is relevant to Ms. Booker's claims. The parties
26 should be prepared to address this issue at the final pretrial conference – specifically,
27 what instances of cephalad migration Plaintiffs intend to present at trial, and why those
28 instances are relevant.

1 Finally, Defendants contend that the probative value of the Recovery filter
2 evidence is substantially outweighed by the risks of unfair prejudice, misleading and
3 confusing the jury, and wasting time. Doc. 9862 at 8-9; Fed. R. Evid. 403. Defendants
4 claim that admission of such evidence will require Bard to introduce its own evidence
5 regarding the design of the Recovery, the technology available at the time, and Bard's
6 investigation of adverse event reports. *Id.* at 9. This may be true, but that often is the
7 result of admitting relevant evidence. With the possible exception of cephalad migration,
8 the Court concludes that known complications with the Recovery filter are plainly
9 relevant to this case. It will not, in the Court's view, mislead or confuse the jury, waste
10 time, or result in unfair prejudice. The motion in limine (Doc. 9862) is **denied**, subject to
11 the Court's consideration of cephalad migration at the final pretrial conference.

12 **B. Defendants' MIL No. 2 (development of the Recovery).**

13 Defendants seek to exclude specific evidence relating to the development of the
14 Recovery device: (1) migration resistance tests, (2) testimony from Dr. Asch regarding
15 his clinical trial of the Recovery, and (3) testimony from Bard employee Kay Fuller
16 regarding the 510(k) submission to the FDA. Doc. 9863 at 2-3. Defendants claim that
17 this "bad act" evidence is irrelevant and inadmissible under Rules 404 and 403. *Id.* at 3-4.

18 The Court cannot conclude that development of the Recovery filter is irrelevant to
19 the G2 filter claims in this case. Bard based its request for FDA clearance of the G2 on
20 the claim that it was substantially equivalent to, and as safe and effective as, the
21 Recovery. Defendants intend to argue at trial that the resulting FDA approval shows that
22 Bard acted responsibly and produced a safe and effective filter. In this context, evidence
23 that the Recovery filter was itself the result of inadequate and incomplete testing, that a
24 doctor involved in the testing concluded that it was inadequate and incomplete, and that a
25 Bard employee reached the same conclusion, is plainly relevant. After considering the
26 Ninth Circuit's four-part test, *see Duran v. City of Maywood*, 221 F.3d 1127, 1132-33
27 (9th Cir. 2000), the Court concludes that such evidence is admissible under Rule 404(b)
28 as probative of Bard's knowledge, intent, and lack of mistake, and that its probative value

1 is not substantially outweighed by the potential dangers set forth in Rule 403.
2 Defendants' motion in limine (Doc. 9863) is **denied**.

3 **C. Defendants' MIL No. 3 (FDA warning letter).**

4 Defendants seek to exclude a 2015 FDA warning letter, contending that it is
5 irrelevant because it constitutes an informal advisory statement by the FDA issued more
6 than seven years after Ms. Booker received her G2 filter. Doc. 9864 at 2-3. Defendants
7 also contend that specific topics in the warning letter are not related to the G2 filter or
8 any other issues in this case. Plaintiffs counter that the letter is an essential piece of
9 evidence to rebut Bard's suggestion that the FDA took no action against Bard and
10 expressed no concerns about Bard filters. Doc. 9927 at 2. Other than one sentence,
11 however, Plaintiffs do not address Defendants' argument that topics in the letter are not
12 related to issues in this case. That sentence argues only that deficiencies in Bard's
13 handling and reporting of filter failures are relevant to this case. *Id.*

14 Many topics in the warning letter lack probative value. Topics 1 and 2 concern the
15 Recovery Cone retrieval system, which is not at issue in this case. *See* Doc. 9864-1.
16 Topic 4(a) concerns the filter cleaning process, which does not appear to be at issue here.
17 Topics 4(b), 5, and 6 concern the Denali filter, a generation of filter developed after the
18 G2 received by Ms. Booker. Topics 3, 7, and 8 concern Bard's complaint handling and
19 reporting processes, but Plaintiffs have not shown why the specific issues raised in those
20 three topics are relevant to this case.

21 The Court concludes that topics 1, 2, 4(a), 4(b), 5, and 6 are not relevant to this
22 case, and will grant the motion in limine with respect to them. The Court cannot tell on
23 the present record whether topics 3, 7, and 8 are relevant; that decision must be made at
24 trial. To avoid the potential prejudice that will result if the warning letter is mentioned
25 but irrelevant, the Court directs Plaintiffs to raise the potential admissibility of topics 3, 7,
26 and 8 outside the hearing of the jury before mentioning the warning letter to the jury.

27 A few other comments are warranted. Plaintiffs argue that Defendants intend to
28 present evidence of the lack of FDA enforcement actions, and to argue that the "FDA's

1 decision not to take any enforcement actions against Bard is probative as to whether Bard
2 acted reasonably in its design and manufacture of the G2 line of filters.” Doc. 9690 at 9.
3 In response, Plaintiffs argue, they should be allowed to show that the FDA did issue a
4 warning letter to Bard. But Plaintiffs’ statement of Defendants’ position is too broad.
5 Defendants argue that they should be permitted to present evidence of “FDA’s lack of
6 enforcement action *regarding Bard’s G2 line of filters.*” Doc. 9690 at 8 (emphasis
7 added). The warning letter did not concern the G2 line of filters, and was issued in 2015,
8 long after Ms. Booker received her G2 filter in 2007. If Defendants open the door at trial
9 by arguing generally that the FDA has never taken enforcement action of any kind, the
10 Court will entertain a request to admit some or all of the FDA warning letter. But on the
11 present record, the Court concludes that the warning letter does not concern issues in this
12 case, with the possible exception of topics 3, 7, and 8, as noted above.

13 If the warning letter becomes relevant, the Court concludes that it should not be
14 barred as hearsay. The public records exception applies to documents that describe
15 “a matter observed while under a legal duty to report” or contain “factual findings from a
16 legally authorized investigation[.]” Fed. R. Evid. 803(8)(A)(ii)-(iii). The warning letter
17 reports the FDA’s factual findings and matters observed under the agency’s investigatory
18 authority, and Defendants have not shown that the letter lacks trustworthiness. Fed. R.
19 Evid. 803(8)(B). The Court will not exclude the letter on hearsay grounds. *See Guthrie*
20 *v. Ball*, No. 1:11-cv-333-SKL, 2014 WL 5314576, at *4 (E.D. Tenn. Oct. 17, 2014)
21 (“Courts have held that FDA warnings . . . are admissible under the public records
22 hearsay exception in Rule 803(8).”) (citations omitted); *Sadler v. Advanced Bionics, Inc.*,
23 No. 3:11-CV-00450-H, 2013 WL 1311148, at *2 (W.D. Ky. Mar. 26, 2013) (finding
24 FDA warning letter admissible under the public records exception where “FDA officials
25 conducted the investigation themselves as a neutral party with motivations to protect
26 public health and safety”); *Sabel v. Mead Johnson & Co.*, 737 F. Supp. 135, 140-41
27 (D. Mass. May 14, 1990) (finding FDA letter recommending a warning label admissible
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1 as a public record where it was based on an investigation pursuant to the FDA's
2 regulation of the safe marketing of prescription drugs).

3 Defendants' motion in limine (Doc. 9864) is **granted**, subject to Plaintiffs' ability
4 to show that topics 3, 7, and 8 are relevant to issues in this case.

5 **D. Plaintiffs' MIL No. 3 (IVC filters as "lifesaving" devices).**

6 Plaintiffs seek to preclude Defendants from putting on a "filters saves lives"
7 defense, or from describing Bard filters as "lifesaving" or "life-extending." Doc. 9867.
8 Plaintiffs state that IVC filters are designed to prevent blood clots from reaching the heart
9 and lungs and any other presumed benefit is "speculative." *Id.* at 2. But preventing
10 blood clots from reaching the heart and lungs saves lives. Defendants cite statistics
11 showing that some 300,000 people die each year from pulmonary embolisms.
12 Doc. 10059 at 2 n.1. Plaintiffs' own expert has testified that the purpose of IVC filters is
13 to prevent pulmonary embolisms, and in this sense the filters can be lifesaving devices.
14 Doc. 10059-3 at 3-4 (Kinney Dep. Tr. 111:17-112:2).

15 Georgia law, which applies in this case, includes a risk-utility analysis for design
16 defect claims. This analysis involves balancing "the risks inherent in a product design"
17 against "the utility or benefit derived from the product." *Banks v. ICI Ams., Inc.*, 450
18 S.E.2d 671, 673 (Ga. 1994). Evidence concerning the benefits of IVC filters is directly
19 relevant to this analysis. Plaintiffs' motion in limine (Doc. 9867) is **denied**.

20 **E. Plaintiffs' MIL No. 4 (IVC filters are the "gold standard").**

21 Plaintiffs seek to exclude evidence and argument that IVC filters are the
22 "gold standard" or the "standard of care" for the treatment of pulmonary embolisms.
23 Doc. 9869. In response, Defendants state that they will not characterize IVC filters as the
24 "gold standard." Doc. 10054 at 2, n.1. The Court need not address this issue further.

25 Defendants do intend to present evidence that IVC filters, including the G2, are
26 within the standard of care for the medical treatment of pulmonary embolisms. *Id.*
27 Defendants assert that such evidence is relevant to the risk-utility analysis for the design
28 defect and negligence claims, and that admission of the evidence will not confuse the jury

1 or result in a mini-trial. *Id.* at 2-4. The Court agrees. Evidence regarding the use and
2 benefits of IVC filters, and when they are called for, will be relevant to the jury's risk-
3 utility analysis, as well as evaluation of the failure to warn claims and Dr. D'Ayla's
4 decision to implant the G2 in Ms. Booker.

5 Plaintiffs express concern that reference to the "standard of care" will confuse the
6 jury concerning the standard of care to be applied in this case. But the standard of care
7 for Bard's design and marketing of IVC filters is entirely distinct from the medical
8 standard of care for when filters should be used to treat patients. To avoid confusion, the
9 parties should refer to the "medical standard of care" when referring to the standard for
10 implanting filters. The parties may also seek a clarifying jury instruction if warranted.
11 Plaintiffs' motion in limine (Doc. 9869) is **denied**.

12 **F. Plaintiffs' MIL No. 6 (nonparties at fault).**

13 Georgia's nonparty at fault statute provides that the "[n]egligence or fault of a
14 nonparty shall be considered if . . . the defending party gives notice not later than 120
15 days prior to the date of trial that a nonparty was wholly or partially at fault." O.C.G.A.
16 § 51-12-33(d)(1). When such notice is given, evidence of the nonparty's fault may be
17 presented to the jury and the jury may apportion fault and damages between the plaintiff,
18 the defendant or defendants, and the nonparty. *Id.*, § 51-12-33(b)-(c).

19 Defendants filed a timely notice identifying Dr. Sarwat Amer as a nonparty at
20 fault. Doc. 8844. The notice states that "Dr. Amer was the diagnostic radiologist who
21 read [Ms. Booker's] lumbosacral spine x-ray on March 26, 2009, which showed her G2®
22 Filter had fractured but with all struts adjacent to the filter in the IVC. Dr. Amer reported
23 only: 'IVC Filter is noted.'" *Id.* at 2. Defendants contend that Dr. Amer failed to
24 properly report the condition of the G2 filter to Ms. Booker's treating physicians, and
25 therefore prevented the physicians from fully evaluating her medical condition and
26 treatment options. *Id.* Defendants further contend that this alleged failure "constituted
27 the sole proximate cause and/or contributing cause to [Ms. Booker's] injuries." *Id.*

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1 Plaintiffs seek to exclude evidence and argument related to (1) the fault or
2 negligence of nonparties not included in Defendants' notice, and (2) the "standard of
3 care" of Ms. Booker's healthcare providers not identified in the notice. Doc. 9871 at 1.
4 Plaintiffs argue that the notice identifies only Dr. Amer as a nonparty at fault, and
5 evidence and argument relating to the negligence or fault of any others is improper under
6 § 51-12-33. *Id.* at 2. For the same reason, Plaintiffs argue that it would be improper for
7 Defendants to present evidence or argument that treatment by other healthcare providers
8 fell below the medical standard of care. *Id.*

9 Defendants state that they will not seek to have the jury apportion fault or damages
10 under the Georgia statute for any healthcare provider other than Dr. Amer. Doc. 10055
11 at 3. Defendants argue, however, that they should be permitted to present evidence of
12 intervening causes of Ms. Booker's injuries. *Id.* Specifically, Defendants contend that
13 "the jury is entitled to hear evidence that Dr. Brandon Kang tore Ms. Booker's tricuspid
14 valve during his attempt to retrieve a fractured strut in her right ventricle," necessitating
15 open heart surgery to repair the valve. *Id.* Defendants intend to argue that Dr. Kang's
16 "medical treatment relates to [Ms. Booker's] damages claim and constitutes an
17 intervening act that severed Bard's liability." *Id.*

18 The parties' arguments require the Court to examine Georgia law related to
19 nonparties at fault and intervening causation.

20 The nonparty at fault statute provides that the "[n]egligence or fault of a nonparty"
21 may be considered by the jury when appropriate notice is given. § 51-12-33(d)(1). The
22 meaning of "negligence" is clear, and the Georgia Supreme Court has defined "fault" to
23 mean "any breach of a legal duty that sounds in tort for the protection of the plaintiff, the
24 breach of which is a proximate cause of the injury about which he complains[.]"
25 *Zaldivar v. Prickett*, 774 S.E.2d 688, 694 (Ga. 2015). Thus, notice is required before a
26 defendant can argue that a nonparty's negligence or other breach of duty proximately
27 caused the plaintiff's injuries, and that some portion of liability and damages should
28 therefore be allocated to the nonparty.

1 A defendant in Georgia can also escape liability by showing that an intervening
2 cause broke the chain of causation between the defendant and the plaintiff. The Georgia
3 Supreme Court has held that the intervening cause need not be “wrongful or negligent.”
4 *Jordan v. Everson*, 806 S.E.2d 533, 534 (Ga. 2017). That court has also held that
5 “[f]or an intervening act ‘to become the sole proximate cause of a plaintiff’s injuries, the
6 intervening act must not have been foreseeable by [the] defendant, must not have been
7 triggered by [the] defendant’s act, and must have been sufficient by itself to cause the
8 injury.’” *Zaldivar*, 774 S.E.2d at 698 (quoting *Ontario Sewing Machine Co. v. Smith*,
9 572 S.E.2d 533 (Ga. 2002)). “[I]f the character of the intervening act . . . was such that
10 its probable or natural consequences could reasonably have been anticipated,
11 apprehended, or foreseen by the original wrong-doer, the causal connection is not
12 broken.” *Id.* (quotation marks and citation omitted).

13 From these authorities, the Court reaches four conclusions:

14 First, with the exception of Dr. Amer, Defendants may not assert at trial that other
15 medical providers, including Dr. Kang, should be apportioned fault under § 51-12-33.
16 For the jury to apportion fault to a nonparty under the statute, Defendants must have
17 given notice regarding the nonparty. *See Monitronics Int’l, Inc. v. Veasley*, 746 S.E.2d
18 793, 804 (Ga. Ct. App. 2013) (noting that Georgia’s nonparty at fault statute “mandates
19 strict compliance”) (emphasis in original). The instructions and verdict form will not
20 permit the jury to apportion fault to any nonparty other than Dr. Amer.

21 Second, Defendants may assert the separate legal doctrine of intervening cause
22 with respect to Dr. Kang or other nonparties not named in the notice. The Court cannot
23 conclude that failure to identify Dr. Kang in the notice forecloses the defense of
24 intervening cause. The nonparty at fault statute specifically provides that “nothing in in
25 this Code section shall eliminate or diminish any defenses or immunities which currently
26 exist, except as expressly stated in this Code section.” O.C.G.A. § 51-12-33(e). The
27 Code section says nothing about the intervening cause defense.¹

28 ¹ The statute does state that negligence or fault of a nonparty “shall be considered”

1 Third, to prevail on their intervening cause defense, Defendants must show that
2 Dr. Kang's intervening act, or the intervening act of any other nonparty, (1) was not
3 foreseeable by Bard, (2) was not triggered by Bard's act, and (3) was sufficient by itself
4 to cause Ms. Booker's injury. *See Zaldivar*, 774 S.E.2d at 698. The jury will be so
5 instructed.

6 Fourth, although Defendants will be precluded from arguing that Dr. Kang or
7 others (besides Dr. Amer) were negligent or at fault for purposes of apportioning liability,
8 the Court cannot conclude that they should be precluded from asserting the fault of these
9 nonparties as an intervening cause of Ms. Booker's damages. Georgia law states that an
10 intervening cause need not be negligent or wrongful, but it also recognizes that such a
11 cause can be negligent or wrongful. *See Jordan*, 806 S.E.2d at 534; *Vega*, 670 S.E.2d
12 at 122. It appears that Defendants intend to suggest to the jury that Dr. Kang was at fault.
13 In a separate motion in limine, Plaintiffs sought to exclude evidence related to Dr. Kang's
14 social media accounts. Doc. 9877. Defendants opposed the motion, asserting that a
15 central issue is "whether Dr. Kang's retrieval was unduly aggressive in this case."
16 Doc. 10063 at 2. Defendants stated that they "will present expert and other evidence that
17 Dr. Kang should have followed a more conservative approach." *Id.* Defendants may
18 make this argument as part of their intervening cause defense. The Court will instruct the
19 jury carefully, making clear that the fault or actions of Dr. Kang (or similarly situated
20 nonparties) may be considered only if the three requirements for intervening cause set
21 forth above are satisfied, while the fault of Dr. Amer may be considered by the jury in
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23 only if proper notice is given. § 51-12-33(d)(1). Arguably, this phrase could be read
24 broadly to suggest that the jury may consider evidence of a nonparty's negligence or fault
25 – for any purpose – only if notice is given. The Court reads the phrase more narrowly.
26 Section 51-12-33 specifically focuses on apportionment of damages, and the Court
27 concludes that "shall be considered" means "considered" in apportioning damages. This
28 reading is reinforced by the statute's express statement that it does not eliminate other
defenses, and seems to comport with Georgia case law. *See Vega v. La Movida, Inc.*, 670
S.E.2d 116, 122 (Ga. Ct. App. 2008) (finding that the defendant was entitled to argue that
a nonparty's act was an intervening cause of the plaintiffs' injuries and noting that § 51-
12-33 concerns apportionment of damages and therefore was inapposite).

1 apportioning fault. Whether the intervening cause defense must apply to all of
2 Ms. Booker's injuries or may be applied to only a discrete part of them is an issue the
3 parties should be prepared to address when jury instructions and the verdict form are
4 finalized.²

5 Plaintiffs' motion in limine (Doc. 9871) is **granted in part and denied in part**.
6 The Court will limit Defendants' nonparty-at-fault and apportionment arguments to
7 Dr. Amer, but deny the motion to the extent Plaintiffs seek to preclude Defendants from
8 asserting that the conduct of Dr. Kang or others constituted an intervening cause.

9 **G. Plaintiffs' MIL No. 13 (the alleged fault of Dr. Amer).**

10 In a related motion, Plaintiffs seek to exclude evidence regarding the alleged fault
11 of Dr. Amer on the ground that Defendants have no expert testimony to support a
12 causation finding by the jury. Doc. 9878. In their notice of nonparty at fault, Defendants
13 state that they rely on the expert reports and deposition testimony of Drs. Daniel Cousin
14 and Piotr Sobieszczyk. Doc. 8844 at 2. Defendants argue that, under Georgia law,
15 causation may be established by linking the testimony of different expert witnesses, and
16 that in this case Dr. Cousin opines that Dr. Amer fell below the standard of care and
17 Dr. Sobieszczyk provides the causation opinion. Doc. 10066 at 2-5.

18 Dr. Sobieszczyk's report references several imaging studies Ms. Booker received,
19 including the radiological exam performed by Dr. Amer in March 2009. Doc. 10067 at 9.
20 He notes that Dr. Amer's exam "showed an IVC filter with one short fragment separated
21 from the filter and pointing up above the filter tip," and another fragment "separated from

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23 ² Defendants argue that they can use the intervening cause defense to assert that
24 Dr. Kang "contributed to" Ms. Booker's injuries. Doc. 10055 at 3. This is not correct.
25 Either his conduct became an intervening cause and broke the causal chain between
26 Defendants and Ms. Booker, eliminating Defendants' liability, or it did not. True, if
27 Defendants are able to show that his actions were the intervening cause for some discrete
28 part of her injury (say, her heart surgery), it may have the same effect as if the jury
apportioned fault and assigned 100% of the heart surgery responsibility to Dr. Kang. But
the jury could reach this result only through the intervening cause analysis and a finding
that the three elements set forth above are satisfied. Defendants cannot use the
intervening cause defense to essentially argue for equitable apportionment – that the jury
should divide the liability between Defendants and Dr. Kang on the basis of their
respective degrees of fault.

1 the filter and moved towards the midline.” *Id.* He refers to the imaging studies as
2 “missed opportunities,” opining that they “clearly defined progressive tilting and strut
3 movement” and “[r]ecognition of this process would have allowed timely retrieval of the
4 filter.” *Id.* at 11, ¶ 2.

5 The Court finds that this opinion, when combined with Dr. Cousin’s opinion
6 regarding the standard of care (Doc. 9878-4 at 4), is sufficient to create a jury issue on
7 whether Dr. Amer is at fault for allegedly failing to report the condition of Ms. Booker’s
8 filter to her treating physicians. Georgia courts have made clear that “[q]uestions
9 regarding causation are peculiarly questions for the jury except in clear, plain, palpable
10 and undisputed cases.” *Moore v. Singh*, 755 S.E.2d 319, 323-24 (Ga. Ct. App. 2014)
11 (citation omitted). This is not one of those cases. *See id.* at 324 (“Based on the combined
12 expert testimony, we conclude that Moore presented evidence creating a jury issue as to
13 whether Dr. Singh would have discovered the fracture if she had properly complied with
14 the standard of care [and] . . . whether the failure to diagnose the fracture during that time
15 led to further complications[.]”). Plaintiffs’ motion in limine (Doc. 9878) is **denied**.

16 **H. Plaintiffs’ MIL No. 9 (statements from associations and other groups).**

17 Plaintiffs seek to exclude evidence of “statements from various associations, trade
18 groups, organizations, societies of physicians, [and] medical providers[.]” Doc. 9874
19 at 1. Plaintiffs first contend that such statements constitute inadmissible hearsay, and
20 possibly hearsay within hearsay. *Id.* at 2. Plaintiffs also contend that admission of such
21 statements through non-experts would evade *Daubert* scrutiny and would violate
22 Rule 403. *Id.* at 2-3. Because Plaintiffs identify no specific statement from any
23 particular association, the Court cannot grant Plaintiffs’ motion. But the Court will
24 address some of the parties’ arguments.

25 Defendants argue that statement by medical societies may be relevant even if they
26 are not offered for the truth of the matter asserted. Doc. 10058 at 2. Defendants note, for
27 example, that the risk-utility test of Georgia law permits a jury to consider “the gravity
28 and severity of the danger posed by [a product’s] design; the likelihood of that danger;

1 the avoidability of the danger, i.e., the user's knowledge of the product, publicity
2 surrounding the danger, or the efficacy of warnings, as well as common knowledge and
3 the expectation of danger[.]” *Banks*, 450 S.E.2d at 675 n.6. Defendants argue that
4 statements from the Society of Interventional Radiologists (“SIR”) about the risks of IVC
5 filters are relevant to several of these factors – the user's knowledge of the product,
6 publicity surrounding the product's danger, and the common knowledge the danger –
7 regardless of whether the SIR's statements are true. Admission for these non-truth
8 purposes, Defendants assert, would not implicate the hearsay rules. Whether statements
9 should be admitted for these purposes must be decided at trial.

10 Defendants also contend that statements by medical societies are admissible under
11 Rule 803(18) even if offered for the truth of the matter asserted. Doc. 10058 at 3.
12 Rule 803(18) provides that a statement contained in a treatise or periodical is excluded
13 from the hearsay rule if (1) “the statement is called to the attention of an expert witness
14 on cross-examination or relied on by the expert on direct examination,” and (2) “the
15 publication is established as a reliable authority by the expert's admission or testimony,
16 by another expert's testimony, or by judicial notice.” Fed. R. Evid. 803(18)(A)-(B).³
17 If deemed admissible, “the statement may be read into evidence but not received as an
18 exhibit.” *Id.* “This limitation ensures that the jurors will not be unduly impressed by the
19 treatise, and that they will not use the text as a starting point for conclusions untested by
20 expert testimony.” 5 *Weinstein's Federal Evidence* § 803.20[1]. Whether Rule
21 803(18)'s requirements are satisfied requires a statement-by-statement inquiry, which
22 must be determined at trial. The party proposing to use a statement under Rule 803(18)
23 must be prepared to show that both requirements are met.

24 Plaintiffs further contend that testimony from non-expert witnesses about
25 statements from medical societies such as the SIR would allow Bard to avoid the scrutiny

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27 ³ On the second requirement, Weinstein's explains: “To establish a proper
28 foundation, the proponent must show that the author of the treatise or article in question
is an authority.” 5 Jack B. Weinstein & Margaret A. Berger, *Weinstein's Federal
Evidence* § 803.20[2] (2d. ed. 2018).

1 of *Daubert*. *Id.* Defendants avow that they will not attempt to offer any expert opinion
2 about such statements through a fact witness. Doc. 10058 at 3. Defendants do state,
3 however, that SIR guidelines were discussed routinely among Bard employees, and that
4 fact witnesses should be permitted to testify about the things they said and the actions
5 they took concerning SIR guidelines. *Id.* at 3-4. If a discussion at Bard that included
6 reference to SIR statements is relevant to an issue in this case and not otherwise
7 objectionable, then a lay witness's recounting of the discussion may be appropriate.
8 The Court will defer ruling on any objections until trial.

9 Defendants contend that even if SIR guidelines are themselves inadmissible on
10 hearsay or other grounds, their experts may rely on the guidelines under Rule 703.
11 Defendants assert that some of their experts have relied on the guidelines in forming their
12 opinions and were not challenged by Plaintiffs in any *Daubert* motion. Doc. 10058 at 3.
13 But even if an expert is allowed to state an opinion formed in part by reliance on the SIR
14 guidelines, that does not mean that the guidelines themselves may be disclosed to the
15 jury. "Rule 703 is not, itself, an exception to or exclusion from the hearsay rule or any
16 other evidence rule that makes the underlying information inadmissible." 4 *Weinstein's*
17 *Federal Evidence* § 703.05[2]. Rule 703 generally does not permit an expert to relay
18 inadmissible evidence – as opposed to the expert's own opinion based on such evidence –
19 to the jury. Indeed, there is "a presumption against disclosure to the jury of information
20 used as the basis of an expert's opinion and not admissible for any substantive purpose,
21 when that information is offered by the proponent of the expert." Fed. R. Evid. 703
22 (2000 Advisory Committee's Note). Thus, if an objection is made, otherwise
23 inadmissible information may be disclosed to the jury under Rule 703 only if the
24 proponent shows that "the probative value of the information in assisting the jury to
25 evaluate the expert's opinion substantially outweighs its prejudicial effect." *Id.*; Fed. R.
26 Evid. 703.

27 If the Court sustains an objection to the admission of the SIR guidelines through
28 expert testimony, and Defendants' believe that the probative value of the guidelines in

1 helping the jury evaluate the expert's opinion substantially outweighs any prejudicial
2 effect, Defendants are instructed to raise this issue with the Court outside the hearing of
3 the jury. If the Court concludes that the SIR guideline evidence may be disclosed to the
4 jury under Rule 703, Plaintiffs may request a limiting instruction that the evidence may
5 be used only for evaluating the expert's opinion and not for substantive purposes.

6 Plaintiffs assert that Bard intends to use the SIR guidelines to establish acceptable
7 failure rates for IVC filter manufacturers, and that use of the SIR guidelines in this way
8 would be misleading and result in unnecessary mini-trials. Doc. 9874 at 3. Plaintiffs
9 further assert that statements from professional organizations with lofty names have
10 limited probative value that is substantially outweighed by the risk of unfair prejudice,
11 confusion, and delay. *Id.* at 3-4. Efficient management of the evidence and adherence to
12 the trial time limits will avoid the risk of mini-trials and delay. Doc. 10058 at 4. The
13 Court cannot conclude on the present record that any probative value the SIR guidelines
14 may have is substantially outweighed by the danger of unfair prejudice. Plaintiffs may
15 object during trial if they believe specific SIR guideline evidence is inadmissible.

16 Finally, Plaintiffs seek to exclude evidence regarding the lack of statements from
17 the SIR and similar organizations. Doc. 9874 at 1-2. Plaintiffs cite to the testimony
18 of one of Bard's experts that, to her knowledge, no medical society has taken the position
19 that Bard retrievable filters carry more risks than other IVC filters. Doc. 9874-2 at 3
20 (Roberts Dep. Tr. 78:9-79:6). Defendants counter that what organizations like the SIR do
21 not say about the risks of IVC filters is relevant to the jury's consideration of the design
22 defect and failure to warn claims. Doc. 10058 at 3. Whether such evidence is relevant
23 and otherwise admissible will depend heavily on context. The Court will make rulings as
24 necessary during trial.

25 Defendants assert that testimony regarding the absence of a statement is not
26 hearsay. Doc. 10058 at 3 n.1 (citing *Llamas v. Seibel*, No. 16-CV-05812-WHO, 2017
27 WL 3782175, at *8 (N.D. Cal. Aug. 31, 2017)). Although this generally is true, silence
28 can be a "statement" for purposes of the hearsay rules where the person "intended it as an

1 assertion.” Fed. R. Evid. 801(a); *see McGiboney v. CCA W. Props., Inc.*, No. 1:13-cv-
2 00214-REB, 2016 WL 843253, at *7 (D. Idaho Mar. 1, 2016) (Rule 801 “explicitly
3 requires that the declarant must actually intend his statement (even if it consists
4 of silence) as an assertion”); *Weinstein’s Federal Evidence* § 801.10[2][b] (“Even silence
5 may be intended as an assertion”). If Plaintiffs believe that testimony regarding the
6 absence of statements from medical societies constitutes inadmissible hearsay, they may
7 object. Plaintiffs’ motion in limine (Doc. 9874) is **denied**.

8 **I. Plaintiffs’ MIL No. 10 (FDA consent for warnings or recalls).**

9 Plaintiffs seek to exclude evidence or argument that Bard needed the FDA’s
10 consent to add warnings to its labels, send warning letters to physicians and consumers,
11 or recall the G2 filter. Doc. 9875. Defendants do not dispute that a medical device
12 manufacturer may send warning letters and voluntarily initiate a recall without FDA
13 consent. Doc. 10062 at 2-4. Defendants will be precluded from presenting evidence or
14 argument to the contrary. Defendants may, however, present evidence and argument
15 explaining the FDA’s potential involvement in any recall effort and the reasons why Bard
16 filters were not recalled. *Id.* at 4.

17 Defendants dispute that manufacturers may add warnings to device labels without
18 FDA consent. Defendants cite 21 C.F.R. § 807.81, but this regulation says nothing about
19 adding warnings to labels. Rather, the significant changes or modifications that may
20 require FDA premarket notification are those affecting the intended use of the device or
21 the “design, material, chemical composition, energy source, or manufacturing process.”
22 21 C.F.R. § 807.81(a)(3)(ii)-(iii). None of these constitutes adding a warning to a label.

23 Defendants also cite an FDA guidance document that notes that a labeling change
24 “meant to significantly improve clinical outcomes, to mitigate a known risk, or in
25 response to adverse events . . . likely requires submission of a new 510(k).” Doc. 10062
26 at 2.⁴ As the Court previously noted, this document is meant only to provide guidance

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28 ⁴ See FDA, *Deciding When to Submit a 510(k) for a Change to an Existing Device, Guidance for Industry and FDA Staff*, at 19 (Oct. 25, 2017), available at <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm>

1 and does not bind the FDA or device manufacturers. Doc. 8872 at 24 n.13. Moreover,
2 the document provides that “manufacturers should monitor device usage and promptly
3 revise the warnings and precautions based on user experience,” and that “[s]ubmission of
4 new 510(k)s for such labeling changes are generally not required.” Guidance Doc. at 22.

5 Defendants cite a regulation that requires FDA approval for label changes or
6 product comparisons, but that regulation applies only to prescription drugs. *See* 21
7 C.F.R. § 201.57(c) (“The requirements in this section apply only to prescription drug
8 products described in § 201.56(b)(1)[.]”). Similarly, the regulation Defendants cite
9 regarding clinical trials concerns the FDA’s approval of new drugs, not medical devices.
10 *See* 21 C.F.R. § 314.126.

11 Plaintiffs’ position, according to Defendants, is that “Bard could have added
12 warnings regarding ‘the increased risks’ of complications ‘associated with its products.’”
13 Doc. 10062 at 2. Defendants contend that the concept of “increased risks” necessarily
14 requires a comparison of the G2 and other filters based on medical device reports
15 (“MDRs”) and data from the FDA’s Manufacture and User Facility Device Experience
16 (“MAUDE”) database, and Plaintiffs’ proposed warning regarding increased risks runs
17 afoul of FDA regulations governing what content may be used in device instructions for
18 use. *Id.* (citing 21 C.F.R. § 201.57(c)). As noted above, however, the cited regulation
19 applies only to prescription drugs. Moreover, Plaintiffs’ motion states that Bard could
20 have warned about increased risks by voluntarily sending letters to physicians and
21 patients. Doc. 9875. Defendants cite no FDA rule or regulation prohibiting such letters.

22 Defendants note that MDR and MAUDE data “alone cannot be used to . . .
23 compare event rates between devices” and cannot be “used in isolation to reach
24 conclusions about the existence, severity, or frequency of problems associated with
25 devices.” Doc. 10062 at 2.⁵ This appears to be correct, but Defendants have not shown
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27 514771.pdf (last visited Feb. 21, 2018).

28 ⁵ See *FDA MAUDE Database*, available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm> (last updated Jan. 31, 2018; last visited Feb. 27, 2018).

1 that FDA consent would be required to provide a warning about increased risks based on
2 other reliable sources.

3 Plaintiffs' motion in limine (Doc. 9875) is **granted** in part. Defendants will be
4 precluded from presenting evidence or argument that Bard needed FDA consent to add
5 any warning to its labels, send warning letters to physicians and patients, or recall its
6 filters. Defendants may, however, present evidence and argument explaining the reasons
7 why Bard filters were not recalled, the FDA's potential involvement in any recall effort,
8 and the fact that warnings about failure rates and increased risks could not be based on
9 MDR and MAUDE data alone.

10 Dated this 1st day of March, 2018.

11
12 *David G. Campbell*
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14 David G. Campbell
15 United States District Judge
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